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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/558,465	04/25/2000	David Scott Dunlop	7546M	8865

27752 7590 01/26/2004

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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/558,465

Applicant(s)

DUNLOP ET AL.

Examiner

Humera N. Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION
Status of the Application

Receipt of the Declaration under 37 CFR 1.132, the request for extension of time (3 months-granted), and the Amendment with attachment (Terminal Disclaimer) all filed 08/11/03 is acknowledged.

The 101 Statutory Double Patenting, Non-statutory Double Patenting, 35 U.S.C. 112-second paragraph and 35 U.S.C. §102 rejections have been *withdrawn*.

Claims 1-9 and 11-34 are pending. Claims 1 and 11-16 have been amended. Claim 10 has been cancelled as requested. Claims 1-9 and 11-34 remain rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 and 11-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramachandran *et al.* (WO 96/29983) in view of Cardin *et al.* (US Pat. No. 5,104,645).

Ramachandran teaches mild aqueous detergent, e.g. shampoo, composition comprising anionic surfactants. Ramachandran teach in claim 1, "a mild aqueous detergent composition...comprising: (a) from about 4 to about 12% by weight of an anionic surfactant...; (c) about 0.3 to 7% by weight of a long-chain alcohol or ethoxylated alcohol averaging about 26 to 40 carbon atoms as a suspending and conditioning agent; (d) an effective amount of a therapeutic agent selected from the group consisting of ...(ketoconazole), ...zinc pyrithione, ...coal tar, ...and mixtures thereof; and (e) about 50 to 85% by weight of water." Ramachandran *et al.* claim in claim 10 that the composition further contains a hair conditioning agent "selected from the group consisting of organosilicone compounds, aminosilicones, water insoluble hydrocarbons, ...and mixtures thereof, present at a level of from about 0.2 to 5% by weight." Ramachandran teach at page 10, lines 4-32, specific hair conditioning agents, including guar hydroxypropyl trimethylammonium chloride.

Ramachandran does not explicitly disclose the bioavailability/coverage index, the conditioning index value, or the minimal inhibitory concentration index value of the composition. Since Ramachandran *et al.* teaches the applicants' instant composition, it

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is deemed that the bioavailability/coverage index, the conditioning index value and the minimal inhibitory concentration index value of applicants' are implicit in the teachings of the reference.

Regarding the molecular weight of the guar derivatives and the charge densities of the cellulose derivatives, it is the position of the Examiner, that one of ordinary skill in the art would be capable of determining suitable molecular weights and charge densities through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters.

Ramachandran et al. do not teach that the zinc salt of 1-hydroxy-2-pyridinethione is in platelet particle form.

Cardin et al. teach antidandruff shampoos comprising an anti-dandruff active being 1-hydroxy-2-pyridinethione salt in platelet particle form having an average particle size from 2 μm to about 15 μm (col. 5, lines 54-58). Cardin *et al.* teach that it is preferential to use approximately 0.3% to about 2% of the pyridinethione metal salt (col. 5, lines 58-60). Cardin teaches that the preferred salt is zinc (col. 6, lines 24-25). Cardin teaches that the synergizers include polyethylene glycols. Cardin also teaches that when the platelet form of a pyridinethione metal salt with a specified particle size is combined with any of a group of specific synergizers in a shampoo matrix that an unexpected substantial improvement in anti-dandruff efficacy is realized (col. 1, lines 37-45).

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It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the anti-dandruff of Cardin *et al.* in the teachings of Ramachandran *et al.* because Cardin *et al.* teach antidandruff shampoos comprising 1-hydroxy-2-pyridinethione salt in platelet particle form having a specified particle size and similarly, Ramachandran *et al.* teach shampoo compositions comprising therapeutic agents, such as antidandruff agents (i.e., ketoconazole, zinc pyrithione, coal tar) in the shampoo compositions. The expected result would be an effective antidandruff composition that exhibits increased efficacy.

Response to Arguments

Applicant's arguments filed 08/11/03 have been fully considered but they are not persuasive. Firstly, the applicant argued regarding the Double Patenting Rejections stating, "Applicants' are submitting a Terminal Disclaimer." Hence, the Double Patenting Rejections have been *withdrawn*.

Secondly, the Applicant argued regarding the 35 U.S.C. 112 second paragraph rejection of indefiniteness stating, "Claim 12 has been amended to delete the term "dispersed" as it was viewed indefinite and unclear." Hence, the 35 U.S.C. 112 second paragraph rejection has been withdrawn, by virtue of the Amendment.

Next, the applicant argued regarding the 35 U.S.C. §102(b) anticipation rejection of Ramachandran *et al.* (WO 96/29983) and the 35 U.S.C. §102(e) anticipation rejection

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of Guskey et al. With respect to Ramachandran et al., the applicant stated, "Ramachandran et al. do not disclose a formulation containing all of the elements of Applicants' claimed invention." With respect to Guskey et al., the applicant stated, "Guskey does not specifically disclose the anti-dandruff particulate claimed by the Applicants. In addition, Applicants' claimed range or anti-dandruff particulate is not disclosed."

These arguments have been fully considered and were found to be persuasive by virtue of the Amendment. Accordingly the anticipation rejections of Ramachandran et al. and of Guskey et al. have been *withdrawn*.

Next, the Applicants argued regarding the 35 U.S.C. 103(a) rejection of claims 1-9, 12-14, 16, 18-20, 30 and 32 over Ramachandran et al. stating, "The Office Action states that Ramachandran et al. and Guskey do not explicitly disclose the bioavailability/coverage index, the conditioning index value, or the minimal inhibitory concentration index values. However, it is deemed that the index values are implicit in the teachings of the reference. Applicants have earlier demonstrated that neither Ramachandran et al. nor Guskey anticipate the instant composition. Applicants submit a Declaration of David S. Dunlop under 37 C.F.R. 1.132. The Declaration demonstrates that surprisingly not all formulas with similar components met the criteria for the specified and required indexes of the present invention. The present invention is neither disclosed nor made obvious in view of Ramachandran et al. or Guskey."

These arguments have been fully considered but were not found to be persuasive. Ramachandran et al., as delineated above, teach mild aqueous detergent, e.g. shampoo, composition comprising anionic surfactants. Ramachandran teach in

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claim 1, "a mild aqueous detergent composition...comprising: (a) from about 4 to about 12% by weight of an anionic surfactant...; (c) about 0.3 to 7% by weight of a long-chain alcohol or ethoxylated alcohol averaging about 26 to 40 carbon atoms as a suspending and conditioning agent; (d) an effective amount of a therapeutic agent selected from the group consisting of ...(ketoconazole), ...zinc pyrithione, ...coal tar, ...and mixtures thereof; and (e) about 50 to 85% by weight of water." Hair conditioning agents, including guar hydroxypropyl trimethylammonium chloride are also taught.

With respect to the bioavailability/coverage index, the conditioning index value, or the minimal inhibitory concentration index values, the Declaration has been fully considered, but was not found to be persuasive. The prior art teaches a similar formulation comprising essentially the same ingredients as that claimed by the instant composition. One of ordinary skill in the art would be well aware of achieving beneficial and suitable bioavailability/coverage indexes, conditioning index values, or the minimal inhibitory concentration index values through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters. The prior art recognizes a shampoo composition, which would essentially provide effective results as those instantly claimed. The Declaration has been carefully considered, but was not found to be persuasive. The Declaration appears to be qualitative rather than quantitative and was not found to be persuasive since in essence the prior art teaches a similar composition with similar components as instantly claimed. Furthermore, it appears that although the Ramachandran et al. reference (Formula C in Declaration) was compared with the instant invention in the Declaration, the Guskey

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reference was not compared with the instant invention by the Applicants in the Declaration. Formula 'B' was cited as being representative of another conditioning shampoo composition. Hence, the Declaration was not found to be persuasive.

Lastly, the Applicants argued regarding the 35 U.S.C. 103(a) rejection of claims 1-13 and 15-34 over Guskey in view of Cardin (US Pat. No. 5,104,645) stating, "Guskey is not available as prior art against the present application under 35 U.S.C. §103(c). Guskey reference only qualifies as prior art under 35 U.S.C. §102(e). Guskey is not available as a 35 U.S.C. §103(a) reference because of the 35 U.S.C. §103(c) provision."

This argument has been fully considered. Accordingly, the 103(a) rejection of Guskey in view of Cardin has been *withdrawn*.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M. After Feb. 04, 2004, the Examiner can be reached at (571) 272-0604.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927 and at (571) 272-0602 after Feb. 04, 2004. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns

January 20, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600